

12-05-05

09/738,212

CASE TX/4-118-8353B



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
EV336718560US	December 2, 2005
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT OF

NEUER ET AL.

U.S. PATENT NO: 6,951,841B2

ISSUED: OCTOBER 4, 2005

FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR  
CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-  
FATTY ACID

Mail Stop Petition  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF FINAL PATENT TERM ADJUSTMENT DETERMINATION  
UNDER 37 CFR §1.705(d)

Sir:

The final patent term adjustment for U.S. Patent No. 6,951,841B2 issued on October 4, 2005 was determined by the PTO to be 527 days which according to the PAIR system was calculated based on the total number of days due to PTO delay, 659 days, less the total number of days due to Patentees' delay, 132 days. Copies of the cover page of U.S. Patent No. 6,951,841B2 and the patent term adjustment history printout from the PAIR system are attached hereto. In making this determination, it appears that the PTO in calculating the total number of days due to PTO delay considered the Board of Patent Appeals and Interferences (BPAI) decision favorable (reversed) when in fact the BPAI decision was unfavorable. A detailed review of the file history of this patent revealed that the patent term adjustment of 527 days was incorrect and that the correct patent term adjustment should be 76 days. Patentees respectfully request that the patent term adjustment be revised to 76 days. The bases for this correction is indicated below.

37 CFR §1.702(b) indicates that the term of a patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the application was filed under 35 U.S.C. §111(a), but not including any time consumed by review by the BPAI. In the present case, the three year period as measured from the application filing date of December 15, 2000 ended on December 15, 2003, however, any days that were consumed by review by the BPAI before December 15, 2003 cannot be included in measuring the three year period and must be added onto the projected issue date of December 15, 2003. The total number of days consumed by the BPAI as determined from the Notice of Appeal dated August 16, 2002 to the BPAI decision dated November 10,

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2004 is 451 days. Accordingly, the addition of 451 days from December 15, 2003 results in an adjusted patent issue date of March 10, 2005.

The patent actually issued on October 4, 2005. Thus, the total number of days of patent term adjustment due to PTO delay as measured from the adjusted issue date of March 10, 2005 to the actual issue date of October 4, 2005 is 208 days.

With respect to 37 CFR §1.704(b), the PAIR system correctly indicated a reduction of patent term adjustment of 132 days due to Patentees' delay as measured from the three-month period from the date of the Office Action of July 18, 2001 to the Patentees' Response received February 27, 2002.

Accordingly, Patentees are entitled to receive a final patent term adjustment of 76 days as determined from 208 days due to PTO delay less 132 days due to Patentees' delay.

It is further noted that U.S. Patent No. 6,951,841B2 is subject to a terminal disclaimer over copending Application Ser. No. 09/547,802 (the '802 application). The PAIR system indicated that as of November 9, 2005 the '802 application is on appeal awaiting decision of the BPAI.

In view of the foregoing, it is respectfully requested that this Request for Reconsideration be favorably considered and that the PTO send out a Certificate of Correction wherein the cover page of the subject U.S. patent reflects a final patent term adjustment of 76 days.

Please charge the \$200 fee required by 37 CFR §1.18(e) and any other fees that may be required to Deposit Account No. 19-0134 in the name of Novartis Corporation. An additional copy of this Request for Reconsideration of Final Patent Term Adjustment is enclosed.

Respectfully submitted,



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Attorney for Applicants  
Reg. No. 37,350

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Attachs.: cover page of U.S. Patent No. 6,951,841B2

Copy of PAIR printout

Extra copy of Request of Reconsideration of Final Patent Term Adjustment  
postcard

Date: December 2, 2005

Printer Friendly  
9/738,212

PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A

POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID



## Patent Term Adjustment History

## Patent Term Adjustment (PTA) for Application Number: 09/738,212

			Days
Filing or 371(c) Date:	12-15-2000	USPTO Delay (PTO):	659
Issue Date of Patent:	10-04-2005	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay(APPL):	132
Post-Issue Petitions (days):	+0	Total PTA:	527
USPTO Adjustment(days):	+0	Explanation Of Calculations	

## Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL (Days)
10-04-2005	Patent Issue Date Used in PTA Calculation		
09-14-2005	PTA 36 Months	127	
08-31-2005	Receipt into Pubs	↑	
08-30-2005	Dispatch to FDC	↑	
08-30-2005	Application Is Considered Ready for Issue	↑	
08-25-2005	Receipt into Pubs	↑	
07-07-2005	Issue Fee Payment Verified	↑	
07-07-2005	Issue Fee Payment Received	↑	
06-14-2005	Workflow - File Sent to Contractor	↑	
04-07-2005	Mail Notice of Allowance	393	
04-04-2005	Notice of Allowance Data Verification Completed	↑	
04-04-2005	Case Docketed to Examiner in GAU	↑	
04-04-2005	Correspondence Address Change	↑	
01-12-2005	Case Docketed to Examiner in GAU	↑	
11-30-2004	Paralegal TD Accepted	↑	
10-06-2004	Mail Notice of Rescinded Abandonment	↑	
10-06-2004	Notice of Rescinded Abandonment in TCs	↑	
10-06-2004	Case Docketed to Examiner in GAU	↑	
10-04-2004	Petition to Revive Application - Granted	↑	
07-15-2004	Petition Entered	↑	
07-15-2004	Workflow incoming petition IFW	↑	
05-03-2004	Workflow incoming amendment IFW	↑	
03-15-2004	Mailing of Abandonment after Board of Appeals	↑	
03-11-2004	Abandonment after Board of Appeals	↑	
01-08-2004	Amendment/Argument after BPAI Decision	↑	
11-10-2003	Mail BPAI Decision on Appeal - Affirmed	139	
11-10-2003	BPAI Decision - Examiner Affirmed	↑	
05-22-2003	Docketing Notice Mailed to Appellant	↑	
05-20-2003	Assignment of Appeal Number	↑	
05-02-2003	Appeal Awaiting BPAI Docketing	↑	
03-26-2003	Mail Reply Brief Noted by Examiner	↑	
03-24-2003	Reply Brief Noted by Examiner	↑	

03-06-2003	Date Forwarded to Examiner	↑
03-06-2003	Case Docketed to Examiner in GAU	↑
02-24-2003	Reply Brief Filed	↑
01-15-2003	Mail Examiner's Answer	↑
01-13-2003	Examiner's Answer to Appeal Brief	↑
11-06-2002	Date Forwarded to Examiner	↑
10-16-2002	Appeal Brief Filed	↑
08-16-2002	Notice of Appeal Filed	↑
08-16-2002	Request for Extension of Time - Granted	↑
05-21-2002	Mail Final Rejection (PTOL - 326)	↑
05-20-2002	Final Rejection	↑
03-15-2002	Date Forwarded to Examiner	↑
02-27-2002	Response after Non-Final Action	↑ 132
02-27-2002	Request for Extension of Time - Granted	↑ ↑
01-31-2002	Case Docketed to Examiner in GAU	↑ ↑
01-31-2002	Case Docketed to Examiner in GAU	↑ ↑
07-18-2001	Mail Non-Final Rejection	↑ ↑
07-16-2001	Non-Final Rejection	↑
06-09-2001	Date Forwarded to Examiner	↑
06-06-2001	Response to Election / Restriction Filed	↑
06-06-2001	Request for Extension of Time - Granted	↑
05-07-2001	Information Disclosure Statement (IDS) Filed	↑
04-20-2001	Mail Restriction Requirement	↑
04-19-2001	Requirement for Restriction / Election	↑
04-13-2001	Information Disclosure Statement (IDS) Filed	↑
04-09-2001	Information Disclosure Statement (IDS) Filed	↑
04-03-2001	Case Docketed to Examiner in GAU	↑
02-27-2001	Application Dispatched from OIPE	↑
02-23-2001	Correspondence Address Change	↑
02-23-2001	Correspondence Address Change	↑
01-30-2001	IFW Scan & PACR Auto Security Review	↑
12-15-2000	Preliminary Amendment	↑
12-15-2000	Initial Exam Team nn	↑

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